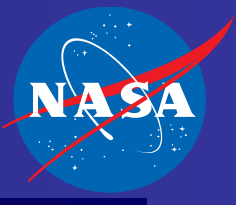




Human Research Program

John B. Charles, Ph.D.
Chief Scientist

Mark J. Shelhamer, Sc.D.
Chief Scientist (Emeritus)



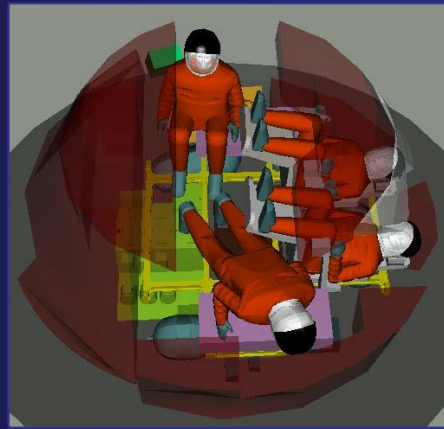
Human Research Program

Human Research Program

- The Human Research Program (HRP) focuses on applied research
- Program goals
 - Perform research necessary to understand and reduce spaceflight human health and performance risks in support of exploration
 - Enable development of human spaceflight medical and human performance standards
 - Develop and validate technologies that serve to characterize and reduce medical risks associated with human spaceflight



Clay Anderson centrifuges Nutrition blood samples during Increment 15



Seat layout for contingency EVA



Example of a study on the effects of center of gravity on performance

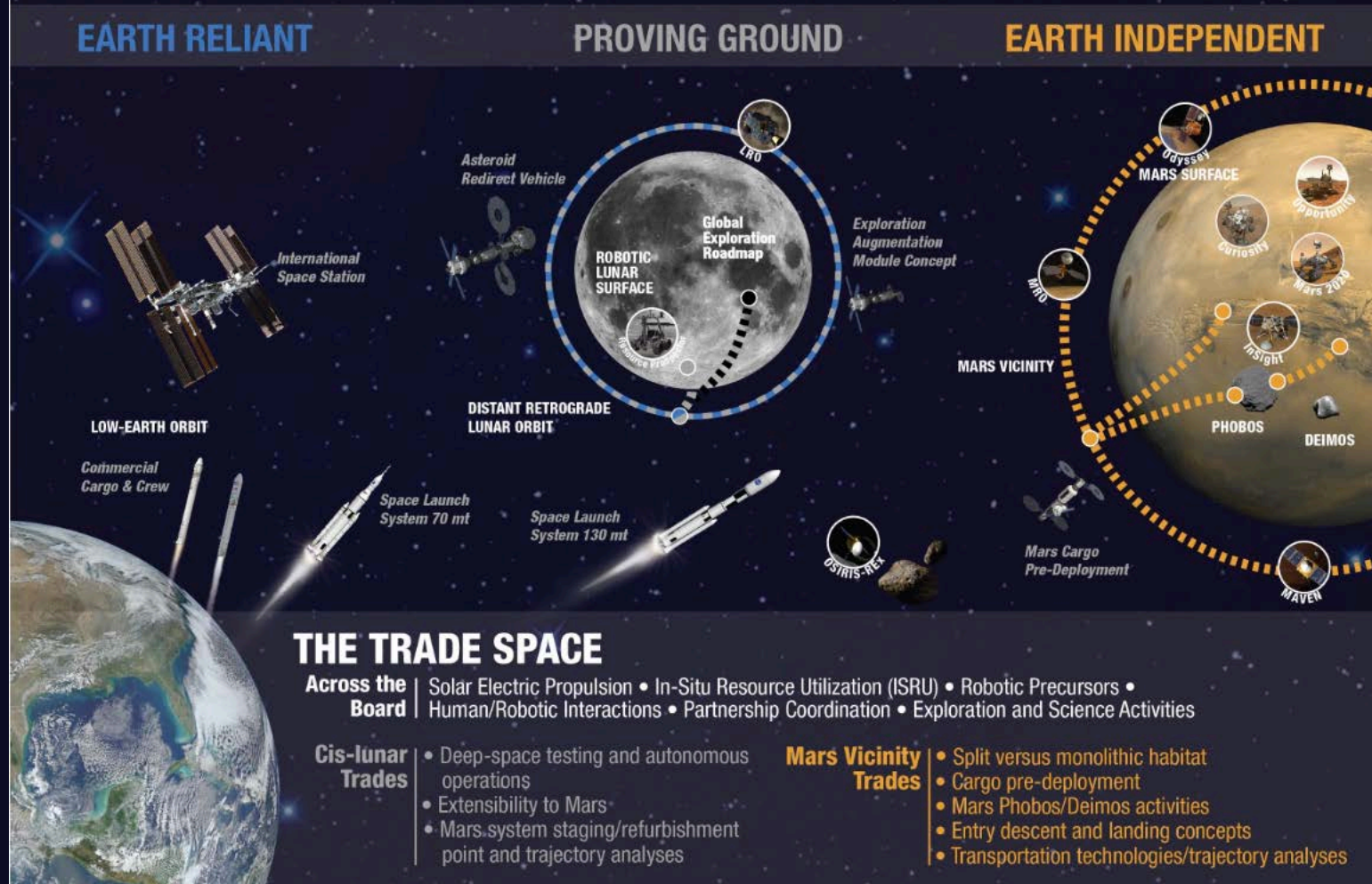
An Applied Research Program

Planned Exploration Activities

Human Research Program

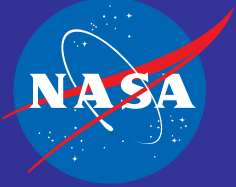
EVOLVABLE MARS CAMPAIGN

A Pioneering Approach to Exploration





One-Year Missions and Twins Study



Human Research Program

- Scott Kelly of NASA and Mikhail Kornienko of Roscosmos launched to the International Space Station on 27 March 2015 and returned on 1 March 2016, the longest space mission ever assigned to a NASA astronaut
- This one-year mission will show if observed physiological trends continue as before or if we are approaching any “cliffs” that will require new treatments while providing new insights
- Possibly five additional one-year missions
- The Twins Study (Scott and Mark Kelly) is NASA’s first foray into 21st-century omics research and will examine differential effects on homozygous twin astronauts associated with differences in exposure to spaceflight factors
- The Twins Study will examine
 - Genome, telomeres, epigenome
 - Transcriptome and epitranscriptome
 - Proteome
 - Metabolome
 - Physiology
 - Cognition
 - Microbiome





Components of HRP

Human Research Program

- HRP is composed of six Elements
 - Human Health Countermeasures
 - *Physiology*
 - Behavioral Health and Performance
 - *Individual and interpersonal*
 - Space Human Factors and Habitability
 - *Interfaces between humans and vehicles/habitats*
 - Exploration Medical Capability
 - *Medical care for missions*
 - Space Radiation
 - *Radiation exposure and biological effects*
 - ISS Medical Project
 - *Infrastructure for flight experiments*
- HRP funds the National Space Biomedical Research Institute (NSBRI) through a cooperative agreement to pursue research that complements the HRP portfolio



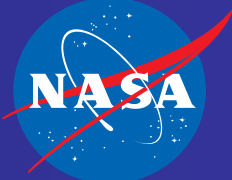
Sunita Williams inserting blood samples into the Minus Eighty Degree Laboratory Freezer



Nutrition SMO

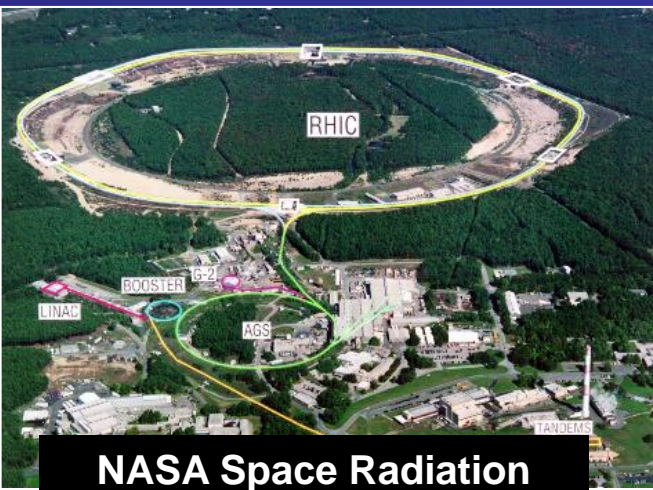


Venues for Conducting Research



Human Research Program

International Space Station



NASA Space Radiation Lab

:envihab



Human Exploration Research Analog





Risk Mitigation

Human Research Program

1. Determine Relevant Risks

- 33 risks and risk factors relevant to exploration within HRP research portfolio
 - Focused on risks that could have a substantial negative effect on an exploration mission

2. Identify gaps in

- a) knowledge
- b) mitigation capability

3. Identify the research products required to fill the gaps

4. Generate research products

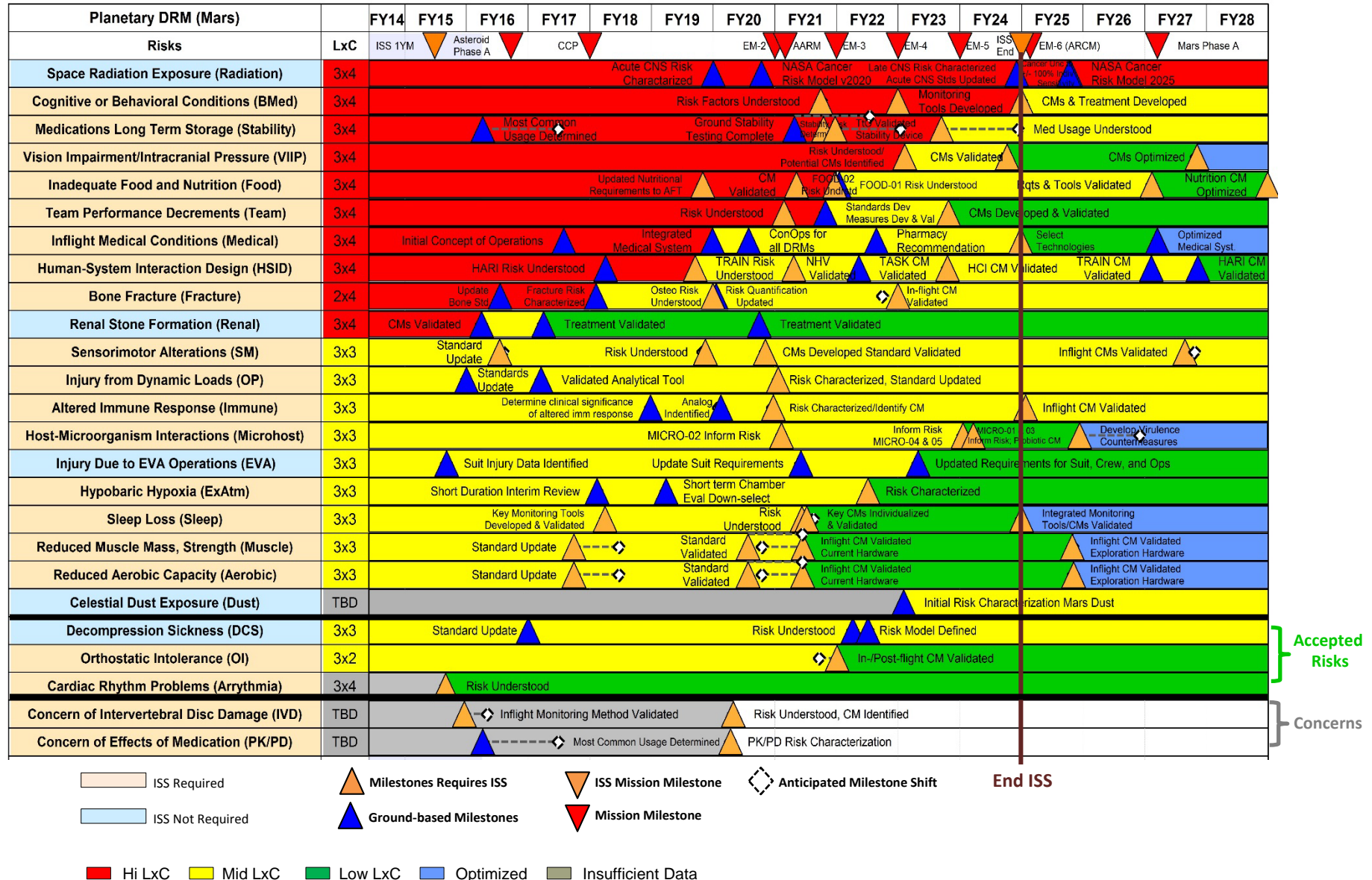
5. Validate research products (as needed)

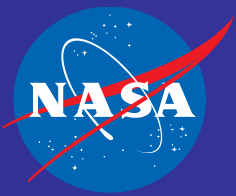
6. Reassess gaps in a) knowledge or b) mitigation capability and return to step 3 as needed

Evidence → Risks → Gaps → Tasks → Deliverables



HRP Integrated Path to Risk Reduction

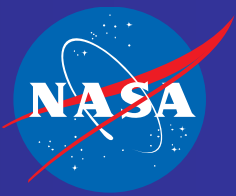




Program Constraints & Goals

Human Research Program

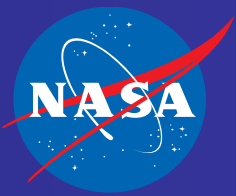
- Constraints on schedule, crew access, and need for risk mitigation are different from those in NIH and NSF solicitations
 - ISS and analogs are limited resources
- An investigation should significantly contribute to the risk-reduction focus of HRP
 - It is not mandatory that it greatly advance the discipline in general or be highly innovative.
 - Results may still be critical in addressing the gaps of the HRP



Statistical Considerations

Human Research Program

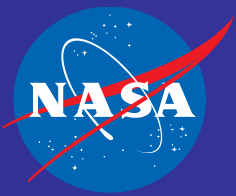
- ISS is significantly oversubscribed with respect to experiments
- Analog facilities also have limitations on subject count and available time
- Robust statistical design of experiments will be part of the solution to oversubscription as well as a way to make more efficient use of limited resources more generally
- Small-n studies might not achieve ideal sample size, statistical power, control of extraneous variables, margin of error, etc.
 - Nevertheless it is critical that data analysis plan is sound
- Proposed sampling procedure, experimental design, and data analysis methodology will be evaluated by statistician on review panel



Flagship Topics

Human Research Program

- Flagship topics represent the primary mechanism for soliciting HRP grants
- Topics are selected from HRP Integrated Research Plan and critical path for each discipline
- Flagship awards typically range from \$50K to \$400K per year, for 3-4 years



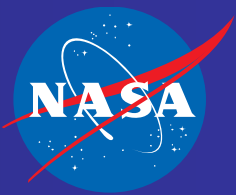
Omnibus Solicitation

Human Research Program

- In order to expedite progress in other than Flagship areas, HRP accepts short-term investigations that address any risk and gap in the Integrated Research Plan
- Omnibus grants last no more than one year and cost no more than \$100K total per award

Basic Investigations for New Investigators (BINI)

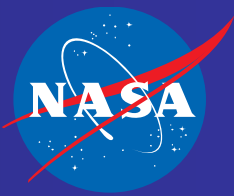
- To explore novel ideas that might not be directly aligned with HRP risks, HRP accepts omnibus proposals in the Basic Investigations category on any aspect of human adaptation to space flight
- Open to new investigators only (no NASA or NSBRI funding as PI in the last ten years)
- Project must adhere to Omnibus guidelines (budget and duration), but can be renewed for one year based on progress



After Merit Review

Human Research Program

- Program Alignment Review follows Merit Review
 - Alignment with Integrated Research Plan, programmatic balance, feasibility (analog definition or flight definition) and cost
- Analog-definition and flight-definition proposals undergo further reviews for feasibility
- Selection Official is HRP Program Manager



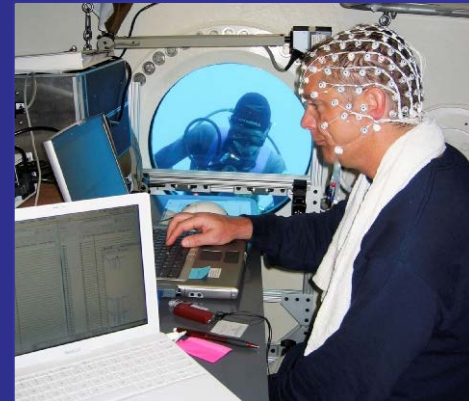
Summary

Human Research Program

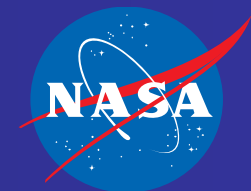
- HRP is focused on understanding and mitigating crew health and performance risks and funding work that directly aligns with those risks. Due to various constraints, HRP does not generally pursue basic research.
- HRP is an applied research program in which the research products must fill the knowledge or mitigation gaps for which research is solicited.
- *Thank you*



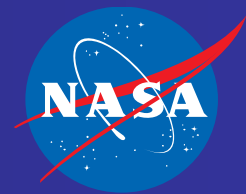
sZLS set up with manikin at UTMB



NEEMO 9 - aquanaut during EEG study



Additional Material



Review Criteria: Significance

Human Research Program

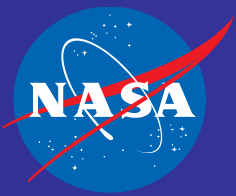
- From the NRA:
 - Does this study address a research emphasis stated in this solicitation?
 - Does the study test a significant hypothesis or produce data that would enable a significant hypothesis to be generated?
 - If the study is non-hypothesis driven, are the data produced needed to understand or reduce the risk addressed by the research emphasis?
 - If the task will produce a software model or tool, how will it serve to better quantify or mitigate a risk?
 - If the aims of the application are achieved, how well will the product(s) address the research emphases?
 - If the aims of the application are achieved, how will scientific knowledge or technology advance?



HRP Risks and Risk Factors

Human Research Program

BHP	Adverse Behavioral Conditions and Psychiatric Disorders
BHP	Performance Decrements Due to Inadequate Cooperation, Coordination, Communication, and Psychosocial Adaptation within a Team
BHP	Performance Errors Due to Fatigue Resulting from Sleep Loss, Circadian Desynchronization, Extended Wakefulness, and Work Overload
ExMC	Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities
HHC	Bone Fracture
HHC	Cardiac Rhythm Problems
HHC	Clinically Relevant Unpredicted Effects of Medication
HHC	Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems
HHC	Crew Adverse Health Event Due to Altered Immune Response
HHC	Decompression Sickness
HHC	Early Onset Osteoporosis Due To Spaceflight
HHC	Impaired Control of Spacecraft, Associated Systems and Immediate Vehicle Egress Due to Vestibular/Sensorimotor Alterations Associated with Space Flight
HHC	Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance
HHC	Inadequate Nutrition
HHC	Injury from Dynamic Loads
HHC	Intervertebral Disk Damage
HHC	Orthostatic Intolerance During Re-Exposure to Gravity
HHC	Performance Decrement and Crew Illness Due to an Inadequate Food System
HHC	Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity
HHC	Renal Stone Formation
HHC	Spaceflight-Induced Intracranial Hypertension/Vision Alterations
SHFH	Adverse Health Effects Due to Alterations in Host-Microorganism Interactions
SHFH	Adverse Health Effects of Exposure to Dust and Volatiles During Exploration of Celestial Bodies
SHFH	Inadequate Critical Task Design
SHFH	Inadequate Design of Human and Automation/Robotic Integration
SHFH	Inadequate Human-Computer Interaction
SHFH	Incompatible Vehicle/Habitat Design
SHFH	Performance Errors Due to Training Deficiencies
SR	Acute and Late Central Nervous System Effects from Radiation Exposure
SR	Acute Radiation Syndromes Due to Solar Particle Events (SPEs)
SR	Degenerative Tissue Or Other Health Effects From Radiation Exposure
SR	Radiation Carcinogenesis



Flight Constraints

Human Research Program

- Implementation of human life sciences research during space flight is limited by various resource constraints such as crew time (before, during, and after flight), up and down mass, and cold stowage
- Experiments that require fewer of these resources will be more feasible to implement
- Flight experiment proposals must represent mature studies strongly anchored in previous or current ground-based or flight research